UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

JOSEPH BARONE,

Plaintiff,

v.

BAUSCH & LOMB, INC., MORCHER GmbH, and FCI OPTHALMICS, INC.,

Defendants.

DECISION AND ORDER

6:17-CV-06877 EAW

INTRODUCTION

On May 9, 2017, Plaintiff Joseph Barone ("Plaintiff") commenced this action by filing a summons and complaint in New York State Supreme Court, County of Monroe, alleging various common law causes of action against Bausch & Lomb, Inc. ("B&L"), Morcher GmbH ("Morcher"), and FCI Opthalmics, Inc. ("FCI") (collectively, "Defendants") resulting from the alleged malfunction of products surgically implanted into Plaintiff's right eye. (*See* Dkt. 1-2 at 3-14). On November 6, 2017, Plaintiff filed an amended complaint (the "Amended Complaint"). (*Id.* at 195-207). B&L then removed this action to federal court on December 20, 2017, alleging federal question jurisdiction. (Dkt. 1 at 6). In support of this proposition, B&L relies upon *Grable & Sons Metal Prod., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 312 (2005), which held that federal question jurisdiction may be asserted over state-law claims that "implicate significant federal issues." B&L subsequently filed a motion to dismiss Plaintiff's Amended Complaint on preemption grounds. (Dkt. 6).

On August 27, 2018, the Court held oral argument on B&L's motion to dismiss. (Dkt. 33). During the motion hearing, the Court raised *sua sponte* the issue of subject matter jurisdiction and required additional briefing on this issue. The Court held further oral argument on February 26, 2019, to address the issue of its subject matter jurisdiction, and the Court reserved decision. (Dkt. 49). For the foregoing reasons, the Court remands this case to New York State Supreme Court, County of Monroe, for lack of subject matter jurisdiction.

BACKGROUND

The following facts are drawn from Plaintiff's Amended Complaint and are taken as true for the purpose of determining whether this Court has subject matter jurisdiction over this action. (Dkt. 1-2 at 195-207). Plaintiff commenced this action due to an alleged product defect found in B&L's Crystalens AO Lens (the "Crystalens"), and Morcher and FCI's Capsular Tension Ring. (*Id.* at 195). On August 20, 2015, these products were implanted into Plaintiff's right eye to improve his vision. (*Id.*). However, these products failed within a matter of weeks, resulting in "multiple follow-up surgeries, extreme pain and discomfort, an inability to see, and permanent injuries." (*Id.*).

The Crystalens is a Class III medical device, which received "Premarket Approval" ("PMA") from the United States Food and Drug Administration (the "FDA") in 2003. (*Id.* at 197). As such, federal standards and regulations govern the manufacture and distribution of this product. (*Id.*). "[A]s a condition of continued approval to distribute" the Crystalens, B&L was required to submit "Adverse Reaction Reports" to the FDA 10 days after B&L became aware of an injury attributable to the device that had not been addressed by the

product's label or that was addressed by the labeling but was "occurring with unexpected severity of frequency." (*Id.*). The FDA also maintains the Manufacturer and User Facility Device Experience ("MAUDE") database, which is open to the public, "known to and discussed by the medical community," and displays information about reported adverse reactions to regulated devices. (*Id.*).

As early as April 2009, B&L became aware that the Crystalens could malfunction due to a defect referred to as "Z syndrome," which caused the device "to assume a 'Z' shape and to stop functioning." (*Id.* at 197-98). Despite this knowledge, B&L allegedly "failed to file Adverse Reaction Reports for all known incidents of Z Syndrome." (*Id.* at 198). As a result, B&L "violated 21 C.F.R. § 803.50(a) and the conditions set by the FDA's initial approval for the Crystalens." (*Id.*).

"[U]pon information and belief," Plaintiff alleges that his Crystalens device "may" have failed as "a result of Z syndrome." (*Id.* at 199). Plaintiff states that "by underreporting the frequency of Z syndrome defects or adverse reactions with Crystalens," B&L "affirmatively misrepresented both to the FDA and to the medical community . . . the unique Z syndrome risks associated with the Crystalens." (*Id.*). According to Plaintiff, because his doctor relied upon B&L's "underreporting [of] Z syndrome incidents," had B&L "communicated adverse events to the FDA," Plaintiff and his doctor would have been "effectively warned . . . of the risks of Z syndrome associated with the Crystalens through the MAUDE database." (*Id.*). Furthermore, had Plaintiff known the "true frequency" at which this defect occurs, "he would not have agreed to the implantation of the Crystalens." (*Id.*).

Plaintiff asserts strict liability and negligent failure to warn claims against B&L, and breach of warranty, negligence, defective design and manufacture, and strict liability failure to warn claims against Morcher and FCI.[1] Plaintiff alleges that B&L "was under a duty to provide adequate warnings of any dangers known or which should have been known regarding" the Crystalens. (*Id.* at 204). B&L "failed to provide adequate warnings to [P]laintiff and to [P]laintiff's eye doctor by failing to report known occurrences of Z Syndrome to the FDA," and as a "direct and proximate" result of this failure to warn, Plaintiff suffered injuries. (*Id.* at 205). Plaintiff further alleges that B&L "owed and breached parallel state and federal duties" by failing to notify the FDA about "post-PMA approval instances of Z syndrome," and that B&L's "underreporting [of] Z Syndrome" was a "violation of state and federal law." (*Id.*). B&L's duty of reasonable care required that it "warn Plaintiff and Plaintiff's eye doctor of the propensity of the product, and to properly instruct relative to the product's implantation, use, and care." (*Id.* at 205-06).

PROCEDURAL HISTORY

On December 20, 2017, B&L removed this action to federal court, alleging that this Court had federal question jurisdiction over this matter. (Dkt. 1). On December 27, 2017, B&L filed a motion to dismiss Plaintiff's Amended Complaint for failure to state a claim. (Dkt. 6). Specifically, B&L contends that Plaintiff's claims are preempted by the Federal

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[1] While Morcher and FCI have not moved against the Amended Complaint, they have joined B&L in arguing that this Court has subject matter jurisdiction to entertain this action and to decide B&L's motion. (Dkt. 39 at 2). Morcher and FCI both anticipate that they "will pursue their preemption arguments regarding the Capsular Tension Ring after resolution of this subject matter jurisdiction issue." (*Id.* at 2 n.1).

Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FDCA"), pursuant to the Medical Device Amendments of 1976, 21 U.S.C. § 360k ("MDA") (Dkt. 7). On February 7, 2018, Plaintiff filed papers opposing B&L's motion. (Dkt. 25). On August 27, 2018, the Court held oral argument on the motion to dismiss and reserved decision. (Dkt. 33). The Court also ordered the parties to file further briefing on the issue of its subject matter jurisdiction. (Dkt. 31). The parties have submitted memoranda and other responsive papers in support of their respective positions on this issue. (Dkt. 38; Dkt. 39; Dkt. 40; Dkt. 41; Dkt. 42; Dkt. 43). The Court held oral argument on February 26, 2019, and reserved decision on the question of subject matter jurisdiction. (Dkt. 49).

DISCUSSION

"Federal courts have a duty to inquire into their subject matter jurisdiction sua sponte, even when the parties do not contest the issue." *D'Amico Dry Ltd. v. Primera Mar. (Hellas) Ltd.*, 756 F.3d 151, 161 (2d Cir. 2014). "It is well-settled that the party asserting federal jurisdiction bears the burden of establishing jurisdiction." *Blockbuster, Inc. v. Galeno*, 472 F.3d 53, 57 (2d Cir. 2006). "In a case removed to federal court from state court, the removal statute is to be interpreted narrowly, and the burden is on the removing party to show that subject matter jurisdiction exists and that removal was timely and proper." *Winter v. Novartis Pharm. Corp.*, 39 F. Supp. 3d 348, 350 (E.D.N.Y. 2014) (citing *Lupo v. Human Affairs Int'l, Inc.*, 28 F.3d 269, 274 (2d Cir. 1994)). "If the court determines at any time that it lacks subject-matter jurisdiction, the court must dismiss the action." Fed. R. Civ. P. 12(h)(3).

"One category of cases over which the district courts have original jurisdiction are 'federal question' cases; that is, those cases 'arising under the Constitution, laws, or treaties of the United States.'" *Metro. Life Ins. v. Taylor*, 481 U.S. 58, 63 (1987) (citing 28 U.S.C. § 1331). In determining whether removal based upon federal question jurisdiction is proper, the "well-pleaded complaint rule" typically governs, which requires a court to consider only allegations in the complaint and not matters raised by the defendant in defense. *See Franchise Tax Bd. of the State of Cal. v. Constr. Laborers Vacation Tr.*, 463 U.S. 1, 9-10 (1983); *see also Beneficial Nat. Bank v. Anderson*, 539 U.S. 1, 6 (2003) ("[A] defense that relies on . . . the pre-emptive effect of a federal statute[] will not provide a basis for removal." (citations omitted)); *see generally Metro. Life*, 481 U.S. at 63 ("The 'well-pleaded complaint rule' is the basic principle marking the boundaries of the federal question jurisdiction of the federal district courts."). "The well-pleaded-complaint rule confines the search for a basis of federal question jurisdiction to 'what necessarily appears in the plaintiff's statement of his own claim in the bill or declaration, unaided by anything alleged in anticipation or avoidance of defenses which it is thought the defendant may impose.'" *Lupo v. Human Affairs Int'l Inc.*, 28 F.3d 269, 272 (2d Cir. 1994) (quoting *Taylor v. Anderson*, 234 U.S. 74, 75-76 (1914)).

Nonetheless, "[t]hree situations exist in which a complaint that does not allege a federal cause of action may nonetheless 'aris[e] under' federal law for purposes of subject matter jurisdiction." *Fracasse v. People's United Bank*, 747 F.3d 141, 144 (2d Cir. 2014). Those situations may occur where "Congress expressly provides, by statute, for removal of state law claims," when "the state law claims are completely preempted by federal law,"

or "in certain cases if the vindication of a state law right necessarily turns on a question of federal law." *Id.* Only the third situation is relevant to the jurisdictional inquiry involved in this case. Courts have termed the application of this principle as the "substantial federal question doctrine." *See Amcat Glob., Inc. v. Yonaty*, 192 F. Supp. 3d 308, 312 (N.D.N.Y. 2016); *In re Standard & Poor's Rating Agency Litig.*, 23 F. Supp. 3d 378, 393 (S.D.N.Y. 2014); *see also Veneruso v. Mount Vernon Neighborhood Health Ctr.*, 933 F. Supp. 2d 613, 619 (S.D.N.Y. 2013) (describing the "substantial federal question doctrine" as a "limited exception[] to the well-pleaded complaint rule"), *aff'd*, 586 F. App'x 604 (2d Cir. 2014).

The Supreme Court has recognized that the "vast bulk of suits that arise under federal law" involve instances where "federal law creates the cause of action asserted." *Gunn v. Minton*, 568 U.S. 251, 257 (2013). Nonetheless, "in certain cases federal-question jurisdiction will lie over state-law claims that implicate significant federal issues." *Grable & Sons Metal Prod., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 312 (2005). However, "[i]t is well-settled that only a 'special and small' category of cases that allege a state-law claim meet the test for arising under federal law pursuant to 28 U.S.C. § 1331." *Martelli v. Niagara Falls Bridge Comm'n*, No. 13-CV-652-A, 2013 WL 3761550, at *2 (W.D.N.Y. July 16, 2013) (quoting *Empire Healthchoice Assurance, Inc. v. McVeigh*, 547 U.S. 677, 699 (2006)); *see NASDAQ OMX Grp., Inc. v. UBS Sec., LLC*, 770 F.3d 1010, 1019 (2d Cir. 2014) ("[T]he Supreme Court has been sparing in recognizing state law claims fitting this criterion.").

"To aid courts in identifying the 'extremely rare exceptions' comprising this group, the Supreme Court has fastened a four-part test." *Mihok v. Medtronic, Inc.*, 119 F. Supp. 3d 22, 27 (D. Conn. 2015) (quoting *Gunn*, 568 U.S. at 257). "[F]ederal jurisdiction over a state law claim will lie if a federal issue is: (1) necessarily raised, (2) actually disputed, (3) substantial, and (4) capable of resolution in federal court without disrupting the federal-state balance approved by Congress." *Gunn*, 568 U.S. at 258. "All four requirements must be satisfied in order for a federal court to have jurisdiction." *Varga v. McGraw Hill Fin., Inc.*, 36 F. Supp. 3d 377, 381 (S.D.N.Y. 2014) (citing *Gunn*, 568 U.S. at 258).

I. The First Requirement—A Federal Issue is Necessarily Raised

"The Supreme Court has partly explained the contours of federal pre-emption under MDA Section 360k(a)." *Gale v. Smith & Nephew, Inc.*, 989 F. Supp. 2d 243, 247-48 (S.D.N.Y. 2013). First, in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), "the Supreme Court . . . held that a state law claim is impliedly preempted under the FDCA if the conclusion that the state law has been violated is based solely on a violation of the FDCA rather than on some independent state law duty." *Nagel v. Smith & Nephew, Inc.*, No. 3:15-CV-00927 (JAM), 2016 WL 4098715, at *3 (D. Conn. July 28, 2016) (citing *Buckman*, 531 U.S. at 349). Then, in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), the Court "ruled on whether Section 360k(a) expressly pre-empted state tort law." *Gale*, 989 F. Supp. 2d at 248. In *Riegel*, the Court held that "[s]tate requirements are pre-empted under the MDA only to the extent that they are 'different from, or in addition to' the requirements imposed by federal law." 552 U.S. at 330 (quoting 21 U.S.C. § 360k(a)(1)). However, *Riegel* "observed that the MDA preemption provision does not bar a state from

providing a damages remedy for claims premised on the violation of FDA regulations, because 'the state duties in such a case "parallel," rather than add to, federal requirements.'" *Burkett v. Smith & Nephew Gmbh*, No. CV 12-4895 (LDW) (ARL), 2014 WL 1315315, at *2 (E.D.N.Y. Mar. 31, 2014) (quoting *Riegel*, 552 U.S. at 330).

"Courts have reconciled *Riegel* and *Buckman* to 'create a narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption.'" *Gale*, 989 F. Supp. 2d at 248 (quoting *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010)). "The plaintiff must be suing for conduct that violates the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing because the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*)." *Sprint Fidelis Leads*, 623 F.3d at 1204 (quotation omitted). "In other words, the plaintiff's state-law claim must 'parallel[ ] a federal-law duty under the MDA' but also exist 'independent[ly]' of the MDA." *A.F. By & Through Fogel v. Sorin Grp. USA, Inc.*, 346 F. Supp. 3d 534, 541 (S.D.N.Y. 2018) (quoting *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1233 (9th Cir. 2013)).

Here, Plaintiff alleges that B&L is liable for state common law torts based upon the violation of a FDA regulation. (*See* Dkt. 1-2 at 195-207). Plaintiff has attempted to thread the needle between *Buckman* and *Riegel* by alleging a violation of a duty created by federal law that also exists independently under New York common law. Accordingly, Plaintiff rightfully concedes that the first *Gunn* element is satisfied. (Dkt. 40 at 10-11).

II. The Second Requirement—The Federal Issue is Actually Disputed

In relation to the second *Gunn* element, Plaintiff argues that because there is no dispute "over statutory interpretation or the validity of the regulations," the fact that the parties dispute whether B&L violated the regulations is immaterial. (*See* Dkt. 40 at 11-13). While there appears to be some authority in the Third Circuit for the proposition that the parties must disagree over the interpretation of a statute or regulation in order to satisfy this prong of the *Gunn-Grable* test, *see MHA LLC v. HealthFirst, Inc.*, 629 F. App'x 409, 414 (3d Cir. 2015) ("The parties have not identified a dispute over the meaning of particular statutory text; rather, HealthFirst generally avers that the parties disagree over the application of the Medicare Act to their situation."); *McLaughlin v. Bayer Essure, Inc.*, No. CV 14-7315, 2018 WL 3535142, at *4 (E.D. Pa. July 23, 2018) ("Bayer has simply not established that there is an actual disagreement about an interpretation of federal law that is material to the claims at issue."), the better position, and the one consistent with many courts within and without this Circuit, is that the second *Gunn* element is also satisfied where the parties disagree over whether there has been compliance with or violation of federal law, *see Broder v. Cablevision Sys. Corp.*, 418 F.3d 187, 195 (2d Cir. 2005) (determining that the federal issue was "actually disputed" where the parties disputed whether a federal statute had been violated); *Callahan v. Sw. Airlines Co.*, No. CV 18-10563-MGM, 2018 WL 5849476, at *5 (D. Mass. Sept. 26, 2018) (finding the second *Gunn-Grable* element satisfied where the complaint "alleges violations of the federally mandated requirements in the [Air Carrier Access Act] regulations" and the defendant "disputes that [p]laintiffs can base claims on violations of these regulations and may

dispute the extent to which it violated at least some of the relevant . . . regulations"), *report and recommendation adopted*, 2018 WL 5846819 (D. Mass. Nov. 7, 2018); *Mihok*, 119 F. Supp. 3d at 28 (finding the second *Gunn-Grable* prong satisfied where it was clear "that 'Medtronic disputes that it violated federal law'" (citation omitted)); *Knox v. Mazuma Credit Union*, No. 15-0288-CV-W-ODS, 2015 WL 3407618, at *2 (W.D. Mo. May 27, 2015) (stating that the "[p]laintiff's claims against [d]efendant necessarily raise federal issues that are actually disputed because" the plaintiff's state law claims "depend on proving [d]efendant violated" federal law); *Maher v. Vaughn, Silverberg & Assocs., LLP*, 95 F. Supp. 3d 999, 1009 (W.D. Tex. 2015) ("Defendants concede that, to the extent the 'federal issue' is whether they violated the FDA regulations, they dispute that issue. Therefore, Maher satisfies the second factor." (citation omitted)); *see also New York ex rel. Jacobson v. Wells Fargo Nat'l Bank, N.A.*, 824 F.3d 308, 317 (2d Cir. 2016) ("[I]n order to establish a false statement or record within the meaning of the [New York False Claims Act], Jacobson must prove at least that the trusts *did not qualify under federal law*. Further, this issue is obviously disputed, as the central premise of Wells Fargo's motion to dismiss was that the trusts *did qualify under federal law*, properly interpreted." (emphases added)).

Here, because Plaintiff contends that B&L violated federal law, and B&L expressly disputes that any such violation took place, the second prong of the *Gunn-Grable* analysis is also satisfied.

III. The Third Requirement—The Federal Issue is Not Substantial

Although this action raises a federal issue that is actually disputed, the issue presented is not sufficiently substantial to warrant the assertion of federal subject matter

jurisdiction. As the Supreme Court has explained, "it is not enough that the federal issue be significant to the particular parties in the immediate suit; [t]he substantiality inquiry under *Grable* looks instead to the importance of the issue to the federal system as a whole." *Gunn*, 568 U.S. at 260. In analyzing this prong, courts frequently look to the dispositive facts of previous Supreme Court decisions to determine whether the instant issue is important "to the federal system as a whole." In *Grable*, the Court described *Smith v. Kan. City Title & Trust Co.*, 255 U.S. 180 (1921) as the "classic example" of where a state law claim "implicate[d] significant federal issues." 545 U.S. at 312. In *Smith*, the plaintiff sought to enjoin the defendant from investing in bonds issued by the federal government on the grounds that the issuance of those bonds was "beyond the constitutional power of Congress." 255 U.S. at 195. Although the plaintiff's arguments challenged the validity of the securities, "[t]he attack upon the proposed investment in the bonds described [wa]s because of the alleged *unconstitutionality of the acts of Congress* undertaking to organize the banks and authorize the issue of the bonds." *Id.* at 199 (emphasis added). Federal jurisdiction was proper in that case because "the controversy concern[ed] the constitutional validity of an act of Congress which is directly drawn in question." *Id.* at 201.

Grable also concerned significant federal affairs. In that case, the Supreme Court determined that there was federal subject matter jurisdiction over the plaintiff's quiet title action because the plaintiff's claim was based upon the alleged failure of the Internal Revenue Service ("IRS") to provide sufficient notice "as defined by federal law." *Grable*, 545 U.S. at 314-15. The *Grable* court stated that "[t]he meaning of the federal tax provision is an important issue of federal law that sensibly belongs in a federal court," and

acknowledged the federal government's "strong interest in the 'prompt and certain collection of delinquent taxes.'" *Id.* (quoting *United States v. Rodgers*, 461 U.S. 677, 709 (1983)). The Court further explained that the federal government "has a direct interest in the availability of a federal forum to vindicate its own administrative action" and that "the ability of the IRS to satisfy its claims from the property of delinquents requires clear terms of notice." *Id.* As the Supreme Court subsequently articulated, the dispute in *Grable* "centered on the action of a federal agency (IRS) and its compatibility with a federal statute." *Empire Healthchoice*, 547 U.S. at 700.

Unlike *Smith* and *Grable*, the instant matter does not challenge any action taken by a federal agency or a coordinate branch of the federal government. *See Mihok*, 119 F. Supp. 3d at 28 (stating that *Grable* and *Smith* "raised questions concerning the construction and validity of federal statutory law, conduct undertaken by the Government under such law, and whether the Government conduct was permissible," and noting that "the resolution of the issue in each case had the potential to affect the Government monumentally"); *see also McCann v. W. Chester Hosp., LLC*, 233 F. Supp. 3d 607, 612 (S.D. Ohio 2017) (finding that the federal issues were not substantial where "[n]one of the issues in this case would affect the Government's operation"); *Knox*, 2015 WL 3407618, at *3 (stating that the substantiality test is satisfied "only when the government's operations are affected by the federal issue" because "[o]nly in such cases could it be stated confidently that if Congress had thought about the issue it would have sensibly concluded the dispute should be resolved by a federal court"). Although Plaintiff's claims are based upon the alleged violation of federal regulatory requirements, this alone is insufficient to

satisfy the substantiality prong of the *Gunn-Grable* analysis. In other words, just because the application of 21 C.F.R. § 803.50(a) "may require a state court to 'grapple with federal law' and perform 'an individualized assessment of both the scope of the [federal regulation] at issue and the particular conduct alleged to fall within (or without) that [regulation,]' [th]is . . . alone [is in]sufficient to 'warrant federal jurisdiction.'" *Mihok*, 119 F. Supp. 3d at 31 (quoting *Standard & Poor's Rating Agency*, 23 F. Supp. 3d at 398); *see Dovid v. U.S. Dep't of Agric.*, No. 11 Civ. 2746 (PAC), 2013 WL 775408, at *12 (S.D.N.Y. Mar. 1, 2013) ("A state law cause of action that requires the interpretation of a federal regulation, by itself, is not sufficiently 'substantial' to create federal jurisdiction."), *aff'd sub nom. Congregation Machna Shalva Zichron Zvi Dovid v. U.S. Dep't of Agric.*, 557 F. App'x 87 (2d Cir. 2014).

"[I]t takes more than a federal element 'to open the "arising under" door,'" *Empire Healthchoice*, 547 U.S. at 701 (quoting *Grable*, 545 U.S. at 313), and the instant matter simply does not rise to the level of substantiality observed in *Smith* and *Grable*, *see, e.g.*, *Carmine v. Poffenbarger*, 154 F. Supp. 3d 309, 318 (E.D. Va. 2015) (finding that disputes relating "to whether medical manufacturers designed, manufactured, and promoted an unreasonably dangerous product," while "clearly important to the Product Defendants," did "not affect the operation of the federal system in the way that was evident in *Smith* . . . or in *Grable*"). As the Third Circuit aptly noted, "[t]he prototypical case of *Grable* jurisdiction is one in which the federal government itself seeks access to a federal forum, an action of the federal government must be adjudicated, or where the validity of a federal statute is in question." *MHA LLC*, 629 F. App'x at 413 n.6. Since this case "does

not call into question the validity of a federal statute or the conduct of a federal actor," it "does not present the unusually strong federal interest required to qualify for the federal forum." *Id.* at 414; *see Veneruso*, 933 F. Supp. 2d at 624 (stating that where a "federal actor" is not involved in an action, the state law cause of action is "unlikely to impact the federal government's interests or its ability to vindicate those interests . . . through administrative action" (quotations omitted)); *Main & Assocs., Inc. v. Blue Cross & Blue Shield of Ala.*, 776 F. Supp. 2d 1270, 1280 (M.D. Ala. 2011) ("*Empire* emphasized that the key factors in *Grable* which made the exercise of federal court jurisdiction appropriate included the fact that the dispute in *Grable* centered on the action of a federal agency and the compatibility of that action with federal law.").

In arguing that the third prong is satisfied, B&L contends that Plaintiff's claims would profoundly affect the federal regulatory landscape of PMA medical devices "because [they] would usurp FDA's exclusive authority to regulate device manufacturers' compliance with post-market reporting requirements, and place it in the hands of the courts—something that the MDA expressly sought to prohibit." (Dkt. 38 at 21 (citations omitted)). This argument overlooks the fact that "Congress anticipated and approved of limited state court analysis and application of the FDA regulations when it decided not to completely preempt parallel state law claims." *Mihok*, 119 F. Supp. 3d at 32; *see Knox*, 2015 WL 3407618, at *3 ("Congress has not preempted the entirety of state regulation nor has it divested state courts of jurisdiction in such matters. This failure is telling and cements the Court's conclusion that the federal issues raised in [p]laintiff's state court petition are not substantial within the meaning of *Gunn*." (footnote omitted)). Indeed, none of the

parties have "challenged the actions of the FDA, which is the agency responsible for enforcement of the regulations at issue," and, "[a]s such, the FDA 'is not a party to this case and accordingly would not be bound by a court's determination of any issues presented at trial or in a pretrial proceeding.'" *Maher*, 95 F. Supp. 3d at 1011 (quoting *Marren v. Stout*, 930 F. Supp. 2d 675, 686 (W.D. Tex. 2013)).

B&L also contends that "[f]ederal question jurisdiction is particularly appropriate here because of the comprehensive federal regulatory scheme for medical devices." (Dkt. 38 at 22). However, to the extent B&L argues "that leaving the suit in state court could undermine the stability and efficiency of Congress's regulatory scheme, . . . this argument . . . presupposes the state court will incorrectly apply federal law." *Knox*, 2015 WL 3407618, at *2; *see also Goade v. Medtronic, Inc.*, No. 13-5123-CV-SW-ODS, 2013 WL 6237853, at *5 (W.D. Mo. Dec. 3, 2013) ("Defendants describe the federal interest in regulating medical devices as substantial—but then, such a claim could be made anytime Congress legislates."). "The desire for uniform interpretation of federal law is related to the argument about expertise (as it presupposes state courts will not properly interpret federal law) and . . . has been found insufficient." *Goade*, 2013 WL 6237853, at *5; *see Gunn*, 568 U.S. at 263 ("[T]he possibility that a state court will incorrectly resolve a state claim is not, by itself, enough to trigger the federal courts' exclusive patent jurisdiction, even if the potential error finds its root in a misunderstanding of patent law."). Furthermore, the fact that whatever decision is rendered upon the merits of Plaintiff's claims will inevitably be reviewed and applied by other courts addressing similar issues does not demonstrate that the federal issue here is important "to the federal system as a

whole." *See Pritika v. Moore*, 91 F. Supp. 3d 553, 560 (S.D.N.Y. 2015) ("Whenever a court applies a given legal standard, that court's opinion could theoretically affect other courts' interpretation of that legal standard. If this were a sufficient basis for 'arising under' jurisdiction, the 'extremely rare exception[ ]' discussed in *Gunn* would swallow up the general rule. . . . Such a result is particularly problematic in cases such as this, where Congress has declined to grant a private right of action under the federal statute." (citation omitted)).

Additionally, the Supreme Court rejected a similar argument that "state use and interpretation of the FDCA pose[s] a threat to the order and stability of the FDCA regime." *Merrell Dow Pharm. Inc. v. Thompson*, 478 U.S. 804, 816 (1986).[2] In *Merrell Dow*, the Supreme Court indicated that the "petitioner should be arguing, not that federal courts should be able to review and enforce state FDCA-based causes of action as an aspect of federal-question jurisdiction, but that the FDCA pre-empts state-court jurisdiction over the issue in dispute." *Id.* While B&L vigorously argues that this case should be dismissed because Plaintiff's claims are preempted (*see* Dkt. 7), Congress has not preempted "parallel" state causes of action that are based on violations of federal law. *See Riegel*, 552 U.S. at 330; *Buckman*, 531 U.S. at 349; *Gale*, 989 F. Supp. 2d at 248. In other words, "[t]hat [B&L] may assert preemption as 'the basis of a federal defense,' or even if such a

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[2] Although the *Grable* court subsequently clarified *Merrell Dow*'s holding, as discussed below, the Supreme Court did not overturn *Merrell Dow* in *Grable*. *See, e.g.*, *Antonetti v. City of New York*, No. 13-CV-771 NGG LB, 2014 WL 4161968, at *5 n.9 (E.D.N.Y. Aug. 19, 2014); *Elmira Teachers' Ass'n v. Elmira City Sch. Dist.*, No. 05-CV-6513 CJS, 2006 WL 240552, at *4 (W.D.N.Y. Jan. 27, 2006).

'defense [wa]s anticipated in the plaintiff's complaint,' removal jurisdiction is neither created nor supported." *Mihok*, 119 F. Supp. 3d at 32 (quoting *Caterpillar Inc. v. Williams*, 482 U.S. 386, 393 (1987)).

At oral argument, B&L contended that because the Amended Complaint focused on violations of federal law, Plaintiff's common law failure to warn causes of action are more properly characterized as federal claims. According to B&L, because Plaintiff's claims are federal in nature, the Court should find that it has subject matter jurisdiction over this action and dismiss the Amended Complaint on preemption grounds. This contention comes closest to the argument anticipated by the Supreme Court in *Merrell Dow*, but, in the context presented here, it confuses the doctrine of "complete preemption" with "ordinary preemption" or "defensive preemption." *See Sullivan v. Am. Airlines, Inc.*, 424 F.3d 267, 272 (2d Cir. 2005).

"Under the well-pleaded complaint rule, the plaintiff is the master of the complaint, free to avoid federal jurisdiction by pleading only state claims even where a federal claim is also available." *Marcus v. AT&T Corp.*, 138 F.3d 46, 52 (2d Cir. 1998). In this case, there is no federal private right to action under the FDCA or the MDA, and Plaintiff was required to plead a parallel state law claim based upon a violation of federal law in order to avoid preemption. Plaintiff's Amended Complaint sufficiently formulates the claims asserted against B&L as parallel state law causes of action based upon the violation of independent federal requirements. (*See* Dkt. 1-2 at 199, 204-06); *Hilyard v. Medtronic, Inc.*, 21 F. Supp. 3d 1012, 1019 (E.D. Mo. 2014) ("In the instant case, plaintiff claims that defendants violated state law. Plaintiff alleges parallel violations of federal law in the

complaint in order to avoid preemption. This is not enough to support jurisdiction under 28 U.S.C. § 1331."); *Goade*, 2013 WL 6237853, at *4 ("Plaintiff's claims against the Medtronic Defendants necessarily raise federal issues that are actually disputed because their state claims are *viable only if* they parallel the FDCA. The Petition thus *must allege* conduct that violates the FDCA." (emphasis added)); *cf. Taldone v. Barbash*, No. 14-CV-2147 (SJF) (AKT), 2014 WL 1800794, at *4 (E.D.N.Y. May 5, 2014) ("Plaintiffs' allegation that defendants violated unspecified 'Federal Laws' is clearly immaterial and made solely for the purpose of obtaining federal question jurisdiction and, thus, is not a colorable federal claim sufficient to provide this Court with subject matter jurisdiction under Section 1331.").

Under the doctrine of complete preemption, "which is a 'narrow exception' to the well-pleaded complaint rule," *Isufi v. Prometal Constr., Inc.*, 927 F. Supp. 2d 50, 57 (E.D.N.Y. 2013), "certain federal statutes are construed to have such 'extraordinary' preemptive force that state-law claims coming within the scope of the federal statute are transformed, for jurisdictional purposes, into federal claims—i.e., completely preempted," *Sullivan*, 424 F.3d at 272. By contrast, "[o]rdinary defensive preemption" is raised in one of "three familiar forms" frequently asserted on a motion to dismiss: "express preemption, conflict preemption, and field preemption." *Id.* at 273. While complete preemption "'transform[s], for jurisdictional purposes,' a plaintiff's state law claims 'into federal claims[,] . . . [t]he Supreme Court has left no doubt . . . that a plaintiff's suit does not arise under federal law simply because the defendant may raise the defense of ordinary preemption.'" *Mihok*, 119 F. Supp. 3d at 32 (quoting *Sullivan*, 424 F.3d at 272-73).

Although B&L urges this Court to characterize Plaintiff's state law claims as federal in nature, this argument conflates these two doctrines of federal preemption. Since Congress contemplated the assertion of parallel state law claims based upon a violation of the FDCA, the complete preemption doctrine does not apply in this context. *See Potts v. Rawlings Co., LLC*, 897 F. Supp. 2d 185, 198 n.7 (S.D.N.Y. 2012) (noting that the complete preemption doctrine will apply where "Congress intended that . . . the statute completely supplant all state law causes of action" (quoting *Nott v. Aetna U.S. Healthcare, Inc.*, 303 F. Supp. 2d 565, 568 (E.D. Pa. 2004))); *see also Marcus*, 138 F.3d at 54 (stating that the complete preemption doctrine "applies only in the very narrow range of cases where 'Congress has clearly manifested an intent' to make a specific action within a particular area removable" (quoting *Metro. Life Ins. Co.*, 481 U.S. at 66)). Indeed, even in cases where "Congress has chosen to regulate the entire field of law in the area in question," complaints alleging "only state law causes of action may not be removed to federal court." *Marcus*, 138 F.3d at 52. Accordingly, B&L's position that the Court should find Plaintiff's claims preempted prematurely places the merits of B&L's dismissal argument before the Court during its jurisdictional inquiry.

In addition, B&L's case support is inapposite, outdated, and otherwise unpersuasive. For example, B&L relies upon *Broder v. Cablevision Sys. Corp.*, 418 F.3d 187 (2d Cir. 2005) and *In re Zyprexa Prods. Liab., Litig.*, Nos. 04-MD-1596, 07-CV-1933, 2008 WL 398378 (E.D.N.Y. Feb. 12, 2008), in support of its assertion that federal subject matter jurisdiction is appropriate in light of the complex federal regulatory scheme applicable to PMA medical devices. (*See* Dkt. 38 at 22-23). However, these cases were

decided without the benefit of the *Gunn* decision. *See Mihok*, 119 F. Supp. 3d at 33 n.6 ("[A]s has been pointed out by other courts, *Broder* was decided without the benefit of *Gunn*, which clarified the substantiality prong of the *Gunn-Grable* test."); *Knox*, 2015 WL 3407618, at *3 (declining to follow *Broder*, in part, because it was "decided before the Supreme Court's decision in *Gunn*"). Moreover, contrary to B&L's suggestion, *Broder* "did not find a substantial federal issue merely because the allegations in the complaint 'involved federal regulation of cable companies.'" *Mihok*, 119 F. Supp. 3d at 32. Rather, the Second Circuit "relied heavily on the fact that Broder's claims involved issues concerning the construction, scope, and application of a particular section of federal law." *Mihok*, 119 F. Supp. 3d at 32; *see Broder*, 418 F.3d at 195 (noting that the defendant not only maintains that it "did not violate the § 543(d) uniform rate requirement," but also "contests, *inter alia*, whether Broder and the class members subscribed in areas that lacked 'effective competition,'" and whether the rates issued were "exempt from the § 543(d) uniformity requirement as promotional rates"). By contrast, Plaintiff's state law claims simply depend upon whether B&L satisfied its reporting obligations under 21 C.F.R. § 803.50(a) "and the conditions set by the FDA's initial approval for the Crystalens." (*See* Dkt. 1-2 at 198).

In addition, *Zyprexa Products* was a "[m]ultidistrict litigation involving [the drug] Zyprexa," and "involve[d] thousands of individuals, organizations and governmental entities all over the United States." 2008 WL 398378 at *1. Zyprexa was "prescribed to over twelve million people worldwide" and brought in "billions of dollars" in annual sales. *Id.* "[T]he national aspects of the Zyprexa litigation—'illustrated by the global resolution

under federal law of fifty state Medicaid liens'—ma[d]e uniformity in treating claims brought in that MDL proceeding desirable." *In re Oxycontin Antitrust Litig.*, 821 F. Supp. 2d 591, 597 n.2 (S.D.N.Y. 2011) (quoting *Zyprexa*, 2008 WL 398378, at *3). B&L has failed to demonstrate the existence of that same national character in this case, which involves a single plaintiff who alleges state law claims based upon B&L allegedly violating its federal reporting requirements. That Congress has decided "(1) not to create a federal remedy for violations of the FDCA, while (2) selectively declining to pre-empt most state causes of action based on FDCA standards[,] . . . strongly suggests there is no need . . . for the 'experience, solicitude, and hope of uniformity that a federal forum offers.'" *Oregon ex rel. Kroger v. Johnson & Johnson*, 832 F. Supp. 2d 1250, 1257 (D. Or. 2011) (quoting *Grable*, 545 U.S. at 312).

As one district court succinctly explained, "[i]f the claim merely requires determining whether defendants did or did not make an FDA-required disclosure, the issue is whether the failure to make the disclosure renders defendants liable under a pleaded theory of state law, which does not necessarily require the resolution of a substantial federal issue." *Windle v. Synthes USA Prod., LLC*, No. 3:11-CV-2591-D, 2012 WL 1252550, at *7 (N.D. Tex. Apr. 13, 2012). The *Windle* court continued with the following and related hypothetical:

> [A]ssume that the FDA required that a patient be furnished certain information before consenting to a particular procedure, and the patient brought suit under state law against the responsible party who failed to furnish the required information. The patient's state-law claim might very well require proof of noncompliance with federal law as an element of the claim, but it would not necessarily require resolving a substantial federal

> issue. The issue could be as straightforward as deciding whether the responsible party did or did not furnish the information required by FDA regulation.

Id.

Similarly, Plaintiff's claims simply require application of the relevant FDA regulations to the facts presented in order to determine whether B&L violated federal law and any parallel New York State duty that may or may not exist. *See Congregation Machna Shalva Zichron Zvi Dovid v. U.S. Dep't of Agric.*, 557 F. App'x 87, 90 (2d Cir. 2014) (stating that "the determination at issue here is a fact-specific application of the regulations . . . that does not implicate the validity of the regulations themselves, or have any other broader effect on federal interests"); *see Marchak v. JPMorgan Chase & Co.*, No. 15-CV-4297 (ILG) (MDG), 2016 WL 3911926, at *6 (E.D.N.Y. July 15, 2016) (same); *Maher*, 95 F. Supp. 3d at 1010-11 (finding the federal issue "not substantial" where the issue of "whether [the d]efendants violated the FDA regulations . . . and subsequently failed to report the incident is a fact-bound, situation-specific set of determinations"). Unlike *Grable*, which "presented a nearly 'pure issue of law,' one 'that could be settled once and for all and thereafter would govern numerous . . . cases,'" Plaintiff's claims are "fact-bound and situation-specific." *Empire Healthchoice*, 547 U.S. at 700 (quotation omitted); *see Newsome v. Bayer Corp.*, No. 7:17-CV-57-KKC, 2018 WL 1906103, at *3 (E.D. Ky. Apr. 23, 2018) ("Defendants offer little or no evidence that applying the federal requirements in issue, particularly reporting requirements, to the parties' conduct will implicate broader or more substantial federal issues, or control numerous other cases going forward"); *In re Vioxx Prod. Liab. Litig.*, 843 F. Supp. 2d 654, 669 (E.D. La. 2012) ("[E]ven if Kentucky

did attempt to prove that Merck failed to comply with FDA disclosure regulations, that federal question would be resolved in the context of whether that conduct constituted a violation of *Kentucky* law; thus, it is hardly a substantial question of federal law.").

B&L also cites to several other out-of-circuit decisions that have been criticized for their approach to the *Gunn-Grable* framework. Specifically, B&L relies on *Burrell v. Bayer Corp.*, No. 1:17-CV-00032-MOC-DSC, 2017 WL 1032504 (W.D.N.C. Mar. 17, 2017), *Arrington v. Medtronic, Inc.*, 130 F. Supp. 3d 1150 (W.D. Tenn. 2014), and *Jenkins v. Medtronic, Inc.*, 984 F. Supp. 2d 873 (W.D. Tenn. 2013), in arguing that the substantiality prong is satisfied because Class III medical devices are extensively regulated by the FDA. (*See* Dkt. 38 at 22). Initially, the Court notes that *Arrington* and *Jenkins* were both authored by the same district judge. Moreover, *Jenkins* "failed to address the [Supreme] Court's concerns in *Gunn*." *Schilmiller v. Medtronic, Inc.*, 44 F. Supp. 3d 721, 731 (W.D. Ky. 2014) (noting that while *Gunn* "did not appear to alter the inquiry under *Grable*, . . . it did emphasize that only a limited subset of cases should fit within the scope of the substantial federal question doctrine"); *see Waitz v. Yoon*, No. 1:14-CV-2875-MHC, 2015 WL 11511577, at *4 (N.D. Ga. June 30, 2015) (stating that *Jenkins* has "been criticized for failing to address the Supreme Court's guidance that places emphasis that 'only a limited subset of cases should fit within the scope of the substantial federal question doctrine'" (quoting *Schilmiller*, 44 F. Supp. 3d at 731)); *see also Carmine*, 154 F. Supp. 3d at 318 (noting that *Arrington* and *Jenkins* applied a pre-*Gunn* Sixth Circuit opinion in resolving the substantiality inquiry); *see generally McCann v. W. Chester Hosp., LLC*, 233 F. Supp. 3d 607, 611 (S.D. Ohio 2017) (declining to follow a post-*Gunn* decision within

the same judicial district where it "did not take into account the United States Supreme Court's holding in *Gunn*," noting that *Gunn* "emphasized the restricted circumstances in which a federal issue could be held as 'substantial'" (quoting *Gunn*, 568 U.S. at 263)). Furthermore, at least one district court in a recent opinion also declined to follow *Burrell* for reasons similar to those outlined above. *See McLaughlin v. Bayer Essure, Inc.*, No. CV 14-7315, 2018 WL 3535142, at *5 (E.D. Pa. July 23, 2018) (acknowledging that "Congress has a significant interest in the regulation of Class III medical devices," but declining to follow *Burrell*, emphasizing the fact that Congress has "provided no corresponding private federal cause of action for violation of federal requirements" and has not preempted all state law claims arising from the violation of federal law); *see also McCann*, 233 F. Supp. 3d at 611-12 ("The vast majority of relevant federal court opinions post-*Gunn* have held that a state tort claim revolving around liability for the misuse of biological products similar to PureGen does not raise a substantial federal issue despite the claim's reliance on FDCA regulations.").

Lastly, to the extent B&L also relies upon *Bowdrie v. Sun Pharm. Indus. Ltd.*, 909 F. Supp. 2d 179 (E.D.N.Y. 2012), the Court finds *Bowdrie* to be inapposite. B&L contends that, like *Bowdrie*, Plaintiff's claims would have broad impacts upon manufacturers of medical devices across the nation. (*See* Dkt. 38 at 25-26). The *Bowdrie* court analyzed whether that case should be remanded pursuant to *Grable* and *Merrell Dow*.[3] 909 F. Supp. 2d at 183-85. The plaintiffs in that action challenged the labeling requirements for "generic

[3] Notably, *Bowdrie* also preceded the Supreme Court's decision in *Gunn*.

Phenytoin Sodium, an antiepileptic manufactured by [the d]efendants." *Id.* at 182. The FDCA permits "generic drug manufacturers to bypass the approval practice by submitting an 'abbreviated new drug application' ('ANDA')—an application showing the proposed generic drug to be the same as a reference listed drug ('RLD') that has already gained FDA approval"—so long as the generic drug is "bioequivalent to and ha[s] the same labeling as the RLD." *Id.* at 181-82. This latter requirement has been coined the "duty of sameness." *See PLIVA, Inc. v. Mensing*, 564 U.S. 604, 613 (2011) ("The FDA . . . tells us that it interprets its regulations to require that the warning labels of a brand-name drug and its generic copy must always be the same—thus, generic drug manufacturers have an ongoing federal duty of 'sameness.'"); *see also Bowdrie*, 909 F. Supp. 2d at 183 (noting that the Supreme Court has given deference "to the FDA's interpretation of its regulations that . . . the labeling of a generic drug must be the same as the labeling of the RLD").

Specifically, the *Bowdrie* plaintiffs claimed that the defendants "failed to meet their ongoing duty of sameness by failing to . . . update their FDA-approved labeling to mirror updated Dilantin labeling[,]" the RLD in that case. 909 F. Supp. 2d at 184. The plaintiffs argued that the defendants should have updated the labeling for Phenytoin Sodium pursuant to the "changes being effected" ("CBE") process, *see* 21 C.F.R. § 314.70(c)(6)(iii), "which enables certain labeling changes to be implemented simultaneous to submitting the changes to the FDA for review," *Bowdrie*, 909 F. Supp. 2d at 183. In other words, the plaintiffs' position implicated the propriety of labeling requirements already approved by the FDA and questioned whether the defendants were required to take further action in light of the Dilantin labeling update in order to comply with their "duty of sameness." *See generally*

Mihok, 119 F. Supp. 3d at 34 (noting that the FDA's position was that "the 'duty of sameness' concerns a 'central premise of federal drug regulation [ ] that the manufacturer bears responsibility for the content of its label at all times'" (quoting *Mensing*, 564 U.S. at 616)).

This context explains why the *Bowdrie* court determined that the plaintiffs' invocation of the duty of sameness "implicate[d] the labeling requirements for generic drug manufacturers *nationwide*." 909 F. Supp. 2d at 184-85 (emphasis added). By contrast, B&L fails to demonstrate how its alleged failure to transmit adverse reaction reports to the FDA would impact medical device manufacturers across the nation, and B&L does not provide a persuasive reason for the Court to apply the reasoning in *Bowdrie* to the facts alleged here. B&L's argument that Plaintiff's claims will somehow "usurp[] FDA's exclusive authority to regulate post-market reporting requirements and plac[e] it in the hands of the courts" (Dkt. 38 at 24), is unsupported and simply not true. Determining whether B&L violated federal reporting requirements in this case does not risk court-imposed "regulation" of post-market reporting requirements. By choosing not to completely preempt parallel state causes of action, Congress anticipated that the courts would resolve those state law claims by applying the MDA and its regulations to the applicable fact-specific circumstances presented. In doing so, the courts in no way usurp any authority from the FDA to regulate PMA medical devices within the boundaries of its discretion and the law.

In sum, "[w]hile the interpretation of FDCA regulations will be of supreme importance to the parties in this case, that interpretation will not be 'significant to the

federal system as a whole' as required by *Gunn*." *McCann*, 233 F. Supp. 3d at 612 (quoting *Gunn*, 568 U.S. at 264). Accordingly, because the federal issue presented is not "substantial," this case does not fall within the "'special and small category' of cases in which arising under jurisdiction still lies." *Gunn*, 568 U.S. at 258 (quoting *Empire Healthchoice*, 547 U.S. at 699). Therefore, the Court concludes that it does not have subject matter jurisdiction over this action because the third prong of the *Gunn-Grable* test is left unsatisfied.

IV. The Fourth Requirement—The Federal Issue is Not Capable of Resolution in Federal Court Without Disrupting the Federal-State Balance

Since the third prong of the *Gunn-Grable* analysis is not satisfied, there is no need to proceed to the fourth prong. However, for the sake of completeness and in the alternative, even assuming that the federal issue presented is sufficiently substantial under the third prong of the *Gunn-Grable* framework, the Court still does not have federal question jurisdiction because the fourth element is not satisfied.

A multitude of cases have held that "accepting federal jurisdiction in a medical device products liability case such as this would disrupt the federal-state balance contemplated by Congress." *Robb v. Bayer Healthcare, LLC*, No. 4:16-CV-1727-RLW, 2016 WL 7235708, at *4 (E.D. Mo. Dec. 13, 2016) (collecting cases). In discussing the fourth element of the *Gunn-Grable* analysis, "other courts have found it 'telling' that Congress chose to neither permit federal jurisdiction, nor completely preclude state jurisdiction, over claims alleging violations of the MDA." *Schilmiller*, 44 F. Supp. 3d at 731; *see Carmine*, 154 F. Supp. 3d at 318 (same); *see generally Buckman*, 531 U.S. at 349

n.4 ("The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions. . . ."). In 1986, the Supreme Court held that "the congressional determination that there should be no federal remedy for the violation of [the FDCA] is tantamount to a congressional conclusion that the presence of a claimed violation of the statute as an element of a state cause of action is insufficiently 'substantial' to confer federal-question jurisdiction." *Merrell Dow*, 478 U.S. at 814. Although some courts subsequently took the position that *Merrell Dow* created a bright-line rule—in the absence of a federal right to action, there cannot be the type of "arising under" jurisdiction described in *Smith*, *see N.Y.C. Health & Hosps. Corp. v. WellCare of N.Y., Inc.*, 769 F. Supp. 2d 250, 255 (S.D.N.Y. 2011) ("*Grable* resolved a circuit split that arose following the Supreme Court's opinion in *Merrell Dow Pharmaceuticals, Inc. v. Thompson*, where the Court seemingly ruled that state law claims implicating federal statutes which did not themselves explicitly provide a private right of action could not confer federal question jurisdiction.")—the *Grable* court clarified that this was not the case, *see Grable*, 545 U.S. at 317 ("*Merrell Dow* cannot be read . . . as overturning decades of precedent, as it would have done by effectively adopting the Holmes dissent in *Smith*, and converting a federal cause of action from a sufficient condition for federal-question jurisdiction into a necessary one." (citation and footnote omitted)). *Grable* explained that "*Merrell Dow* should be read in its entirety as treating the absence of a federal private right of action as evidence relevant to, but not dispositive of, the 'sensitive judgments about congressional intent' that § 1331 requires." 545 U.S. at 318.

Put another way, although "the lack of a private right of action for FDCA and MDA violations does not control the federal question jurisdiction analysis, it is a relevant factor for the Court's consideration." *Fenn v. Philips Elecs. N. Am. Corp.*, No. CIV.A. 14-96-DLB-JGW, 2015 WL 632154, at *6 (E.D. Ky. Feb. 13, 2015) (citing *Grable*, 545 U.S. at 318). Moreover, "[t]he combination of no federal cause of action and no preemption of all state remedies . . . is 'an important clue to Congress's conception of the scope of jurisdiction to be exercised under § 1331.'" *Anders v. Medtronic, Inc.*, No. 4:14CV00194 ERW, 2014 WL 1652352, at *7 (E.D. Mo. Apr. 24, 2014) (quoting *Grable*, 545 U.S. at 318).

B&L suggests that the assertion of federal jurisdiction in this case would not disrupt the federal-state balance approved by Congress because "[o]nly a small fraction of medical devices receive[] premarket approval." (Dkt. 38 at 26). However, this exact argument has been persuasively rejected by other courts. *See Carmine*, 154 F. Supp. 3d at 319 (rejecting the "argument that only a 'small percentage' of a 'tiny [fraction]' of medical devices is as heavily regulated as" the device at issue, stating that this "legal analysis would not be confined to Class III medical devices" and would apply, at minimum, "to all medical devices" (quotation omitted)); *Anders*, 2014 WL 1652352, at *7 (same); *Goade*, 2013 WL 6237853, at *6 (same). In fact, because "the MDA permits individuals to bring state law causes of action alleging violations of duties that parallel the federal requirements[, i]t would be entirely inconsistent with this structure to conclude that Congress intended all such state law causes of action to be brought in federal court." *McLaughlin*, 2018 WL 3535142, at *5.

It is also significant that "the Supreme Court in *Merrell Dow* indicated its unwillingness to open up federal courts to all state law tort claims involving medical devices." *Schilmiller*, 44 F. Supp. 3d at 731; *see Grable*, 545 U.S. at 318 (stating that the *Merrell Dow* court saw the absence of a private cause of action and federal preemption "as a missing welcome mat, required in the circumstances, when exercising federal jurisdiction over a state misbranding action would have attracted a horde of original filings and removal cases raising other state claims with embedded federal issues"). Furthermore, "[t]he Supreme Court has consistently made clear 'the need to give due regard to the rightful independence of state governments—and more particularly, to the power of the States to provide for the determination of controversies in their courts[.]'. . ." *Liana Carrier Ltd. v. Pure Biofuels Corp.*, 672 F. App'x 85, 92 (2d Cir. 2016) (quoting *Merrill Lynch, Pierce, Fenner & Smith Inc. v. Manning*, 136 S. Ct. 1562, 1573 (2016)).

Here, Plaintiff's causes of action are formulated as state law claims frequently resolved by New York State courts. The fact that those claims are based upon the violation of federal law does not alter their essential character as state causes of action. *See Liana Carrier Ltd.*, 672 F. App'x at 92 ("The fact that the state court's analysis of breach will necessarily turn on the requirements of federal securities law does not change the underlying nature of [p]laintiffs-[a]ppellants' claims, which are determined as a matter of course by the state courts every day—and whose resolution of any embedded federal issue, if decisive to the case, would ultimately be subject to possible Supreme Court review."). While B&L correctly states that by enacting the MDA, Congress "swept back *some* state obligations and imposed a regime of detailed federal oversight," *Riegel*, 552 U.S. at 316

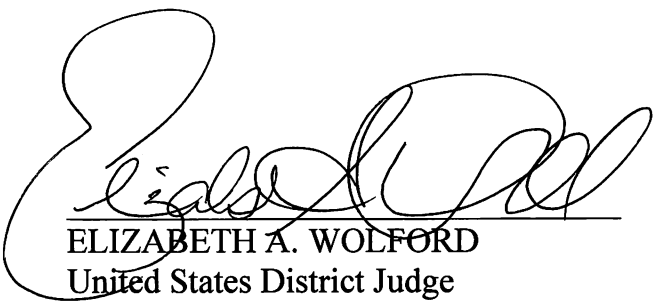
(emphasis added), the fact that Congress did not preempt *all* state law causes of action counsels against federal jurisdiction.

Therefore, the Court concludes that the exercise of federal jurisdiction over Plaintiff's state law claims would disrupt the federal-state balance contemplated by Congress under the MDA, thus further justifying a finding that this Court lacks subject matter jurisdiction.

CONCLUSION

For the foregoing reasons, the Court concludes that it does not have subject matter jurisdiction over this action, and the case is therefore remanded to the New York State Supreme Court, County of Monroe. The Clerk of Court is instructed to mail a certified copy of this Decision and Order, with a clear reference to Supreme Court, County of Monroe, Index No. E2017000711 to the clerk of the state court, and then to close the case.

SO ORDERED.



ELIZABETH A. WOLFORD
United States District Judge

Dated: March 12, 2019
Rochester, New York